IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:) .	$C_{O_{\bullet}}$
David A. WILLIAMS, et al.)	VOL
Serial No. 09/394,867)	
Filed: September 13, 1999)	Via Hand Delivery
METHODS FOR ENHANCED RETROVIRAL-MEDIATED GENE TRANSHER) 1	Examiner: Maria Marvich Group Art Unit 1632

INFORMATION DISCLOSURE STATEMENT

SUBMITTED TO OFFICE AFTER MAILING OF A FINAL OFFICE ACTION
BEFORE RECEIVING WRITTEN NOTIFICATION OF NEW ISSUES OF
PATENTABILITY RAISED BY OFFICE AFTER RESPONDING TO SAID FINAL
OFFICE ACTION

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Please find enclosed an Information Disclosure Statement filed after receiving a Final

Office Action on the merits but before the Applicant had an opportunity to respond to a new set

of objections raised after Final.

This Information Disclosure Statement is being submitted after the mailing date of a final Office Action and prior to payment of the issue fee, and thus a fee of \$180.00 is enclosed. Should any additional other fee be required, please charge such fee to Deposit Account No. 23-3030, but not to include any payment of issue fees. This Information Disclosure Statement is not accompanied by a statement under 37 CFR § 1.98(d) 1. Accordingly the Applicants respectfully

requests pursuant to the provisions of 37 CFR 1.56, 1.97, and 1.98, consideration of the references listed on the attached PTO/SB/08 forms and/or the additional information identified below.

A legible copy of each foreign patent document and publication listed on the PTO/SB/08 form is enclosed.

For each non-English language reference listed on the attached SB/08 form(s), reference is made to:

Japanese Patent No. 2-97397 correspondence to European Patent Application Publication No. 0 349 342 A2, a copy of which is also enclosed.

Japanese Publication No. 2-311498 corresponding to Kimizuka et al. U.S. Patent No. 5,102,988, and Buropean Patent Application Publication No. 0 399, 806 A2. A copy of the European publication is enclosed.

The filing of this Information Disclosure Statement shall not be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in \$1.56(b).

Respectfully Submitted,

John J. Emanuele, Jr.

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		4,727,059	9		02-0)1-19BB	Binder			
		4,839,464	4	•	08-0	1-1989	McCarthy		· · · · · · · · · · · · · · · · · · ·	
		4,980,279	9		12-0	1-1990	Peters			
		6,004,681	ť		04-0	2-1991	Boyse			
		5,019,646	5		05-2	8-1991	Furcht			
	:	5,102,988	3		04-0	7-1992	Kimizuka		•	
		5,116,368	3	<u></u>	05-2	6-1992	McCarthy		·	
•		5,124,165	3		08-2	3-1992	Reich			
		5,175,096	3		12-2	9-1992	Hook			
		5,188,959			02-2	3-1993	Haberman		<u></u>	
		5,198,423	3	,	03-3	0-1893	Taguchi .	<u> </u>		
		5,229,172	2	A1 .	07-2	0-1993	Cahalan et al			
		5,299,172	2		03-2	9-1994	Badger		•	
		5,409,825		-	04-2	5-1995	Hoffman			

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		"Bubble	Boy sa	ved by gene therepy	r, BBC News, April 3, 2000		·				
		"Cell-Cel Garland	ll Adher Publish	sion and the Extrace ling Co., New York	ellular Matrix", Molecular Biolo	gy of the Cell, 19	83, pp. 673-713,				
		ANDERS	ANDERSON, W. FRENCH, "Prospects for Human Gene Therapy",								
		ANDERS No. 256,	7, NO3 108 .qq	/. FRENCH, "Humai 8-813	n Gene Therapy - SCIENCE*	SCIENCE, May	8, 1992, Vol./Issue				
		APPERL Hemator Hematol	oiatic (danosinə Deamii Long-Term Expi	rase in Murine ression ^a , Amer. Soc.						
		ASHWE Vol./Issu	LL, G. I e No. 5	ET AL., "Carbohydra 1, pp. 531-554	te-Specific Receptors of the	Liver", Ann. Rev.	Biochem, 1982,				
		BERNAF Biol., 198	RDI ET 87, Vol.	AL, "Lýmphoid Pre /Issue No. 105, pp.	cursor Cells Adhere to Two D 489-498	ifferent Sites on I	Fibronectin", J. Cell				
	·	of in vitro	active n. 350-	ted progenitors with -354	ene transfer into hematopoleti out maπow ablation°, Proc. N	ati. Acad. Sci. US	SA, 1994, Vol./Issue				
		Rhesus I	Monkey 4+ Bon	r Hernatopoietic Cell e Maπow Cells* Ric	In vivo expression of a Murine is of Multiple Lineages After F and 1993 Vol /Issue No. 82:	Retroviral-mediate 7 pp. 1975-1980	ed Gene Transfer				
		BODINE Gene Tra Vol /Issu	, DAVII ensfer i e No. 8	D M., ET AL., "Deve nto Rhesus Monkey 7_pp_3738-3742	lopment of a High-Titer Retro Hematopoletic Stem Cells",	virus Producer Co Proc. Natl. Acad.	ell Line Capable of Sci. USA, 1990,				
	BRADLEY, T.R. ET AL., "The Growth of Mouse Bone Marrow Cells in Vitro", Aust. J. Exp. Blol. Med. Sci., 1986, Vol./lesue No. 44, pp. 287-300										
		BROXME Human (EYER, I	H.E. ET AL., "Umbli Transplantation", Bl	illical Cord Blood Hernatopoietic Stem and Repopulating Cells in Blood Cells, 1991, Vol./Issue No. 17, pp. 313-329						
				H.E. ET AL., "The fu , pp. 321-329	iture of Umbillical Cord Trans	portation", Umbili	cal Cord Blood				
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			gene-trar No 23 o	nafer: 1 n <u> 187</u> -	mplications 194	s for humi	lfate as an effective alternation gene therapy", Journal of	of Vi	rological Metho	ds, 1989, Vol/issue		
			CRISTIA Gene De No. 90. p	livery a	nd Express	"Hepatic sion in Pri	Gene Therapy: Adenovirus mary Hepatocytes", Proc.	En Nati	hancement of F . Acad. Sci. US	Receptor-Mediated A, 1993, Vol./Issue		
			DILBER, MS. ET AL., "Basic fibroblast growth factor increases retrovtral-mediated gene transfer into human hematopoietic peripheral blood progenitor cells", Exp. Hematol, 1994, Vol./issue No. 22:12, pp. 1129-1133									
			EMONS, in Gynec	G. ET ologica	AL., "The t I Cancers",	Use of Lui , Hum. Re	teinizing Hormone Releasi eprod., 1994, Vol/Issue No	ng H 9:7	lormone Agonis 7, pp. 1364-137	its and Antagonists 9		
ú∢.	Ţ.	-	FICHARD No. 14, p	D ET A p. 515-	L., "Anothe 531	r Look at	Gollagen V and XI Molecu	es",	Matix Biology,	1994; Vol./issue		
				ion wit			d resistance to taxol for per g retroviral vector, Exp. He					
			Blood Pro	ogenito	r Cells Afte	er Introduc	Ex Vivo Expansion and Selection of Human CD34+ Peripheral action of a Mutated Dihydrofolate Reductase cDNA via Retroviral 1995. Vol./Issue No. 85:2 pp. 566-574					
			FRIEDM/ 1276-128	ann, t	HEODORE	E, "Progre	ss Toward Human Gene T	hen	py", SCIENCE	, June 1989, pp.		
			Principles	of Ge	netics, , Vo ons. New Y	ol/Issue N York	Somatic-Cell Tene Therap lo. Chapter 24 Genetic Eng	jine	ering and the F	ugure, pp. 645-648,		
			GLUCKIV	AN, E.	ET AL., "E No. 45, pp	Sone Marr	ow Transplantation in Fand 1	coni	Anaemia", Briti	sh J. of Haem.,		
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		HOWELL Breast C:	A. El ancer,	TAL., "Re The Lan	esponse to cet, 1995, \	a Specific Antioestro /ol./lesue No. 345, p	ogen (ICI 1 p. 29-30	82780) in Tamo	oxifen-Resistant		
		HOWS, J Lancet, J	HOWS, J.M. ET AL, "Growth of human umbilical cord blood in longterm haemopoietic cultures", Lancet, July 11, 1992, Vol./Issue No. 340, pp. 73-78								
tall's a	.,	KARLSS Transfer	ON, ST , Blood	TEFAN, " I, 1991, V	Treatment o	of Genetic Defects in o. 78:10, pp. 2481-2	Hematop 492	oietic Cell Func	tion by Gene.		
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		KIMIZUK Expresse	A ET A d in Es	L., "Prod scherichia	luction and a coli", J. Bi	Characterization of I ochem., 1991, Vol./I	Functional ssue No. 1	Domains of Hu 10:2, pp. 284-2	man Fibronectin 191		
		KLIJN, J. Hum. Rej	G.M. E prod., 1	T AL., "F (994, Vol	re-Clinical I./Issue No.	and Clinical Treatme 9 Supp. 1, pp. 181-1	nt of Brea 189	st Cancer With	Antiprogestins",		
		Using HL 419-422	A-Matc	ched Sibf	ing Umblika	_	British J.	Haem., 1993, V	ol./Issue No. 85, pp.		
	KORNBLIHTT, A.R., ET AL, "Isolation and characterization of cDNA clones for humans and bovine fibronectin", Proc. Natl. Acad. Sci. USA, 1983, Vol./Issue No. 80:11, pp. 3218-3222										
		polypeption No. Abstr	de chai act 12/	ins differi /14. pp. 5	ng in the nu 853-5868	n fibronectin: cell sp imbar of Internal rep	eats", Nuc	leic Acids Res.,	1984, Vol./Issue		
	KORNBLIHTT, A.R., ET AL, "Human fibronectin: molecular cloning evidence for two mRNA species differing by an internal segment coding for a structural domain", EMBO J., 1984, Vol./Issue No. Abstract 3/1, pp. 221-226										
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		LIM, Retro	ET AL., "l	.ong-Term Expre cted Hematopoie	ession etic S	n Of Human Adenosine Dean item Cells", Proc. Natl. Acad.	ninase In Mice Tr Sci. U.S.A., 198	ensplanted With 9, Vol./Issue No. 86,		
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		with i	righ efficie	incy by a retrovir	al ve	or cells purified from cryopres ctor and expanded ex vivo wi ne" Blood, 1994, Vol./Issue I	ith stable integrat	ion and expression		
**		LUSI	EY, B.D.	ET-AL., "Stem (Cell F	actor, Interleukin-3, and Inte Hematopoietic Stem Cells*,	rleukin-6 Promote	e Retroviral-		
		MAR Differ	KOWITZ, ent Plasn	D. ET AL., "A Se ids", J. Virol., 19	afe P 988, \	sckaging Line for Gene Trans /ol./tssue No. 62:4, pp. 1120	sfer: Separating \ -1124	/inal Genes on Two		
						tion and Use of a Safe and E 167, pp. 400-408	fficient Amphotro	pic Packaging Cali		
		MCG marre	LAVE P. I	ET AL., "Interacti nvironment", Bio	lon o	f primitive human myeloid an elis, 1994, Vol./Issue No. 20:	d lymphoid proge 1, pp. 121-128	ntors with the		
		Glyco 5:6. r	peptide L	igand for the Asi 0	alogi	ed Delivery of DNA Using YE yeoprotein Receptor", Biocor	jugate Chem., 19	194, Vol./issus No.		
		MILL	ER, A. DL pp. 456-4	ISTY, "Human G	ene '	Therapy Comes of Age", Nat	ure, June 11, 199	2, Vol./Issue No.		
		MOO Humi 1399	an Bone N	RI A. ET AL., "S larrow Long-Ten	itrom m Cu	al Support Enhances Cell-Fr lture-Initiating Cells", Blood,	ee Rectroviral Ve 1992, Vol./Issue	ctor Transduction of No. 79:8, pp. 1393-		
MOORE, M.A., ET AL., "Gene Therapy: New Frontiers, an International Symposium", Meeting Abstract: Dubiln, Ireland, Sept. 18-21, 1994, pp. 1-2										
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							Group Art Unit	1632				
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							expansion of cord blood-deri 0, pp. 468-481	ved stem cells an	d progenitors",			
			GO, ET irkhäus				Problem and Tertiary Structu	re Prediction*, 19	94, pp. 492-496,			
			NOJIMA, YOSHIHISA ET AL., "Ligation of VLA-4 on T Cells Stimulates Tyrosine Phosphoryla 105-kD Protein", J. Exp. Med., 1992, Vol./Issue No. 175, pp. 1045-1053									
		G	lucocer	ebrosio	daso G	ene in Mice a	nsfer and Sustained High Expression of the Human and Their Functional Macrophages Following Transplantation of coviral Vector, Proc. Natl. Acad. Sci. Usa. 1992. Vol./Issue No. 89					
		P	ATEL E	TAL.,	"Gene	ration of inter	leukin-2 Secreting melanoma erapy, 1994, Vol/Issue No. (Cell Populations				
13°- 1		. P	ATEL, I	ET AL., ation",	"Loss Scienc	of Adhesion ce, 1984, Vol.	of Murine Erythroleukemia Cells to Fibronectin During Erythroid /Issue No. 224, pp. 996-998					
							zation of hemopoletic cell po 93, Vol./Issue No. 21, pp. 74		nan cord blood			
							ffication, immunochemical P /issue No. 82, pp. 803-831	roperties, and Bio	logical Activities",			
			UOSLA 75-413		., "Fibr	onectin and II	s Receptors", Ann. Rev. Blo	chem., 1988, Vol./	lssue No. 57, pp.			
							t Of Biologically Active Doma 6, pp. 7277-7281	lins in The Fibron	ectin Molecule", J.			
							ct of fibronactin and its recornin", Jpn. J. Cancer Res., 19					
		Q D	ifferent	Messe	nger R	NAs Possibly	ver Fibronectin Complementa Encoding the α and β Subur 25 pp. 4936-4941					
		S		C., ET	AL., "		ed Targets for Retrovirus Inte	egration", Cell, 198	38, Vol./Issue No.			
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		Hon 309	mone S	-Gelon	in Conj	ugate", Jour	oxins: Preparation and Char nal of Biological Chemistry,	1989, Vol./Issue N	lo. 264:6, pp. 3089-			
	,	Ret	rovial '	Transi	er of H	uman MDR1'	Selection of Drug Resistant , SCIENCE, July 3, 1992, V	ol./Issue No. 257,	pp. 99-100			
		initi	ating I	Long-T	erm He	matopoiesis	zation and Partial Purificatio In Vitro", Blood, 1989, Vol./	lesue No. 74-5, pr	o. 1563-1570			
		Stro	TOKSOZ ET AL., "Support of Human Hematopolesis in Long-Term Bone Marrow Cultures by N Stromal Cells Selectively Expressing the Membrane-Bound and Secreted Forms of the Human Homolog of the Steel Gene Product, Stem Cell Factor", Proc. Natl. Acad. Sci. USA, 1992, Vol./									
		TOL	CHE	R, A.W	/., "Cun	rent Status o	f Post-chemotherapy Tamos ue No. 8/11, pp. 39-43	ifan in Early Brea	st Cancer",			
		TOF	RRE, I	D. ET / eficien	AL., "In oy virus	teraction,of h ". Fems. Imr	uman plasma fibronectin wi nunol. Med. Microbiol., 1994	th viral proteins of I, Vol./Issue No. 8	human -2, pp. 127-131			
		TSA fibro	vi, SC oblest	HWIC and f	KWANI ibronec	NET AL., "Di tin", Blood, 1	ifferential binding of erythrold and myeloid progenitors to 1987, Vol./Issue No. 69-6, pp. 1587-1594					
		. Env	elopa	A-WIT Protei	n to Re	N, S. ET AL., direct the Ho	"Modifications in the Bindingst Range of Retroviral Vectors	g Domain of Avian ors", J. Virol., 1994	Retrovirus I, Vol./Issue No.			
		VAN Rhe	N BEU sus M N 199	ISECH Ionkey 2 Vol.	EM. V. s Trans Assue	splanted with	Long-Term Expression of H Retrovirus-Infected Bone-M 640-7644	arrow Cells", Proc	. Natl. Acad. Sci.			
		VAN	DER	SLUI	JS, "DH	ferential Adh	erence of Murine Hematopo ogy, 1994, Vol./Issue No. 22		bsets to			
		VAF	RMUS	, HAR	OLD, "F	Retroviruses*	, SCIENCE, June 10, 1988,	pp. 1427-1434				
		Into Elbr	Single onecti	e Lined in". J. j	age Clo Exo. Me	nogenic Prog ad., 1991, Vo	ntiation of Primitive Human genitors is Accompanied by 1/Issue No. 174, pp. 693-70	Atterations in Thei	r Interaction with			
	WAGNER, J.E. ET AL., Transplantation of Umbilical Cord Blood After Myeloblastive Therapy: Analysis of Engraftment*, Blood, 1992, Vol./Issue No. 79:7, pp. 1874-1882											
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•		patients",	Blood.	, 1993, Vol./Issue N	embilical cord blood transplantation: Report of results in 26 p. Abstract, pp. 82-86a				
		WATT ET Epithelium	AL., " in Hu	Adhesion Receptor man Thymus", Exp	s are differentially expressed erimental Hematology, 1992	d on Developing Thymocytes and t, Vol./issue No. 20, pp. 1101-1111			
		WIGINTO! Deaminas	N. DA e", Bio	N A. ET AL., "Compochemistry, 1986, V	olete Sequence and Structur ol./lesue No. 25, pp. 8234-8:	e of the Gene for Human Adenosine 244			
		WILLIAMS	S, DA\ is", Na	/ID A. ET AL., "Fibra dure, 1991, Vol./las	onectin and VLA-4 in Haems ue No. 352, pp. 438-441	atopoiatic Stem Cell-Microenvironment			
		suspension	n cultu	ıre", Biood Cells, 19	94, Vol./issue No. 20, pp. 4				
•		Proc. Nati	nter C Acad	D34+ hematopoietic <u>Sci_USA_1995_V</u>	cell transduction with cell-fi ol./issue No. 92 no. 4372-4	lucocerebrosidase gene in nonhuman ree retroviral vector preparations", 378	Ö		
		XU, LINCH patients us Hematolog	HENG, Sing a 14199	, ET AL., "Correction clinically acceptable 34. Vol./Issue No. 2:	n of the enzyme deficiency in eretroviral supernatant trans 2. np. 223-230	n hamatopoletic cells of Gaucher sduction protocol", Experimental			
		YAO ET A	L, "Pi te The	rimary myoblast-me erapy, 1994, Vol./Iss	diated gene transfer: persis sue No. 1:2, pp. 99-107	tent expression of human factor IX in			
		ZIEGLER, Blood, 199	B.L. E 2, Voi	TAL, "Phenotype //issue No. 80 Supp	e analysis of umbilical cord (CB) blood CD34 cell subpopulations*, pp. 1, pp. 408A				

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